

amalsed[®] direct - wet

INSTALLATION, OPERATION & CARE MANUAL



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Disclaimer and Exclusion of Liability

medentex cannot be made liable for damages resulting from failure to observe the information contained in this manual, modifications to the product not approved by medentex or the use of spare parts not manufactured or approved by medentex.

Table of Contents

Contact information	2
Disclaimer and Exclusion of Liability	2
Table of Contents	3
Section I – Introduction.....	5
General Information.....	5
Conventions used in this manual.....	5
Explanation of symbols used on equipment and in this manual	5
Safety Instructions	6
Proper use.....	6
Qualifications of personnel	6
Risk posed by waste water from dental practices	6
Safety notices and labels on the products	6
Classification & Certification	7
Product definition and description.....	8
Section II – Pre-Installation.....	9
Site Requirements	9
Typical Installation Options.....	9
Option 1 - amalsed® direct – Wet.....	9
Section III – Installation & Initial Operation	10
Illustrated Parts Breakdown and Replacement Parts List.....	10
amalsed® direct S – Wet (In-line) Kit:	10
amalsed® direct S - Wet (In-line) Kit (cont.):	11
amalsed® direct L – Wet (In-line) Kit:.....	12
amalsed® direct L - Wet (In-line) Kit (cont.):.....	13
Installation	14
amalsed® direct - Wet (In-line)*	14
Section IV – Care	15

Replacing the amalgam separator	15
Cleaning and disinfecting agents	17
<i>Section V – User Service Information</i>	<i>18</i>
Individual Product Information	18
Troubleshooting	18
<i>Section VI - Warranty & Product Support Services</i>	<i>19</i>
<i>User’s log - Daily cleaning actions</i>	<i>20</i>
<i>User’s log - Amalgam separator replacement details.....</i>	<i>21</i>

Section I – Introduction


General Information


This manual contains the installation, operation, care and repair instructions, and user service information for medentex dental amalgam separator kits:

- amalsed® direct S - for up to 3 operating units or 2 users*
- amalsed® direct L - for up to 6 operating units or 4 users*

The amalsed® direct is designed to provide trouble-free service when installed, operated and cared for according to the procedures set forth in this manual.

Conventions used in this manual

	WARNING Warning of a harmful situation Possible consequences: Danger to health.
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	NOTICE Notice about a harmful situation Possible consequences: Damages to product or surrounding objects.
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Explanation of symbols used on equipment and in this manual



Attention. Warning of dangerous or immediate danger to health.



CE compliant medical product complying with ISO 13485.


Safety Instructions


Proper use

The amalsed[®] direct is a multi-fit amalgam separator that acts as a central point for cleansing waste water in dental practices and separating amalgam from waste water by sedimentation. It is designed to remove 99.2% of waste amalgam from dental waste water. The medentex amalsed[®] green amalgam separator cartridge is **ISO 11143** approved and test results can be delivered upon request.

Qualifications of personnel


This manual is intended for trained dental staff and dental technicians who are aware of regulations and standard application to the place of installation.

	NOTICE Trained and authorized personnel with appropriate plumbing qualifications only are permitted to install and commission the amalsed [®] direct - amalgam collector kit!
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	NOTICE The amalgam separator must be replaced by accredited service technicians or instructed members of dental office staff only (dental office staff must be briefed by the service technician during product installation and commissioning).
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Risk posed by waste water from dental practices

Waste water from dental practices including water used during dental treatment can contain harmful heavy metals and potentially infectious materials.

	WARNING Always wear protective clothing when working with the amalsed [®] direct and when replacing the amalgam separator(s). Protective clothing includes protective gloves and facemask that are supplied with the installation kit.
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Safety notices and labels on the products

Warning label on the amalgam separator:

	WARNING Attention. Warning of infectious / hazardous wastes.
---	--

Classification & Certification



Proprietary Name:	amalsed [®] max; medentex amalsed; medentex SRAB 99S
Classification Name:	Unit, Operative Dental, Accessories.
Product Code:	NRD
Device Class:	1
Regulation Number:	872.6640
Medical Specialty:	Dental
Registered Establishment Name:	MEDENTEX GMBH
Owner/ Operator:	medentex GmbH
Owner/Operator Number:	10036262
Establishment Operations:	Manufacturer



amalsed[®] green - medical product complying with CE-Norm.
 Certification body No: **0434** – Det Norske Veritas (DNV)



amalsed[®] green - amalgam separation efficiency according to **ISO 11143**.

Product definition and description

Technical description and data

The amalsed[®] direct is an amalgam collector kit, designed to be connected to any existing dental vacuum system.

SPECIFICATIONS		
Product Name	amalsed [®] direct S	amalsed [®] direct L
Number of Amalgam separators	1	2
Max. Number of operatories / Users to be connected simultaneously.	3 ops. / 2 users	6 ops. / 4 users
Tray dimensions H x W x D [inches]	9.75" x 15" x 13"	9.75" x 15" x 13"
Separator dimensions H x W x D [inches]	7" x 10.75" x 6.5"	7" x 10.75" x 6.5"
Air-Water Separator dimensions H x W x D [inches]	15.5" x 10.5" x 9"	15.5" x 10.5" x 9"
Flow rate [gal/min.]	0.8	1.6
Connection size [In]	1"	1"
Amalgam separation efficiency	99.2%	99.2%
Expected time to fill	1 year	1 year

Section II – Pre-Installation

This chapter assists in making an easy and sound installation. For direct assistance, please contact an authorized dealer or a medentex technical service representative.

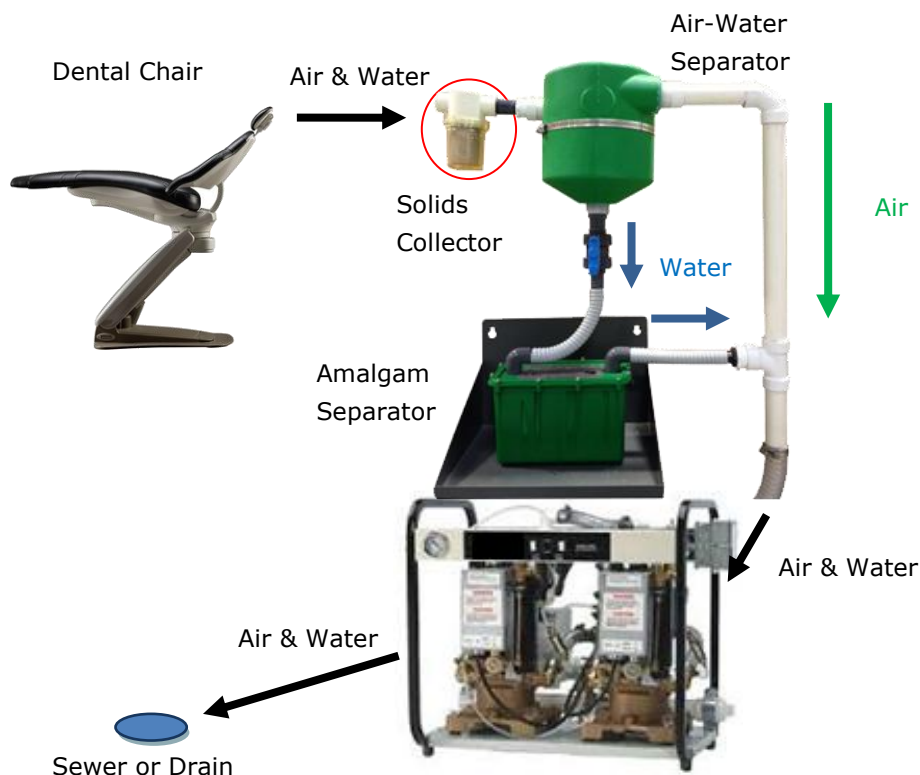
!	NOTICE
	Liquid ring pumps with two or more horsepower must be fitted with an amalsed® direct L separator kit with two separator cartridges (Product ID: A0US1802)

Site Requirements

The amalsed® direct is designed to enable easy installation. All basic components are delivered within the starter kit. Prior to installation, the following requirements must be available:

Typical Installation Options

Option 1 - amalsed® direct – Wet (Product ID: A0US1801 & A0US1802)



!	NOTICE
	Prior to installation of amalgam separator kit, move solids collector from the suction intake of the wet-ring pump to the intake of the green buffer tank *medentex recommends a large kit with offices that have two wet ring pump & 7+ operatories to accommodate for the large amount of liquid flowing through the system

Section III – Installation & Initial Operation

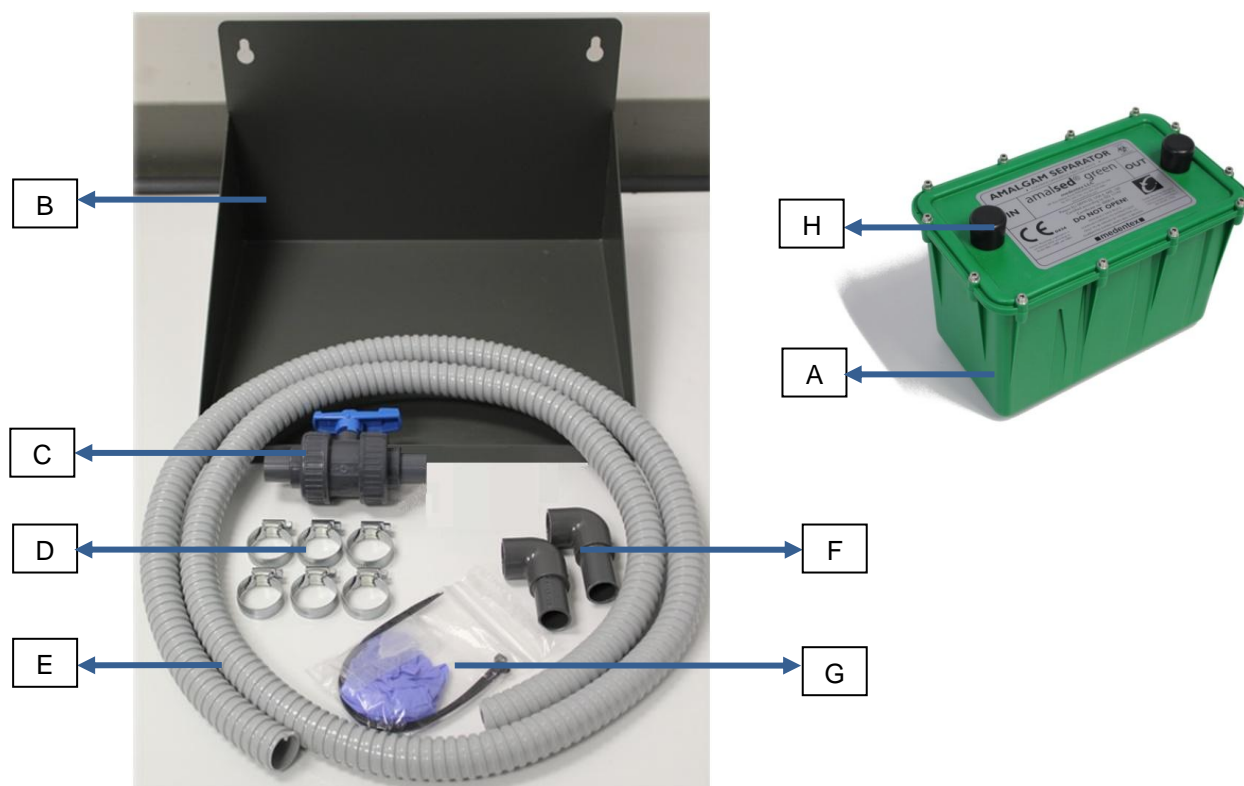
Illustrated Parts Breakdown and Replacement Parts List



NOTICE

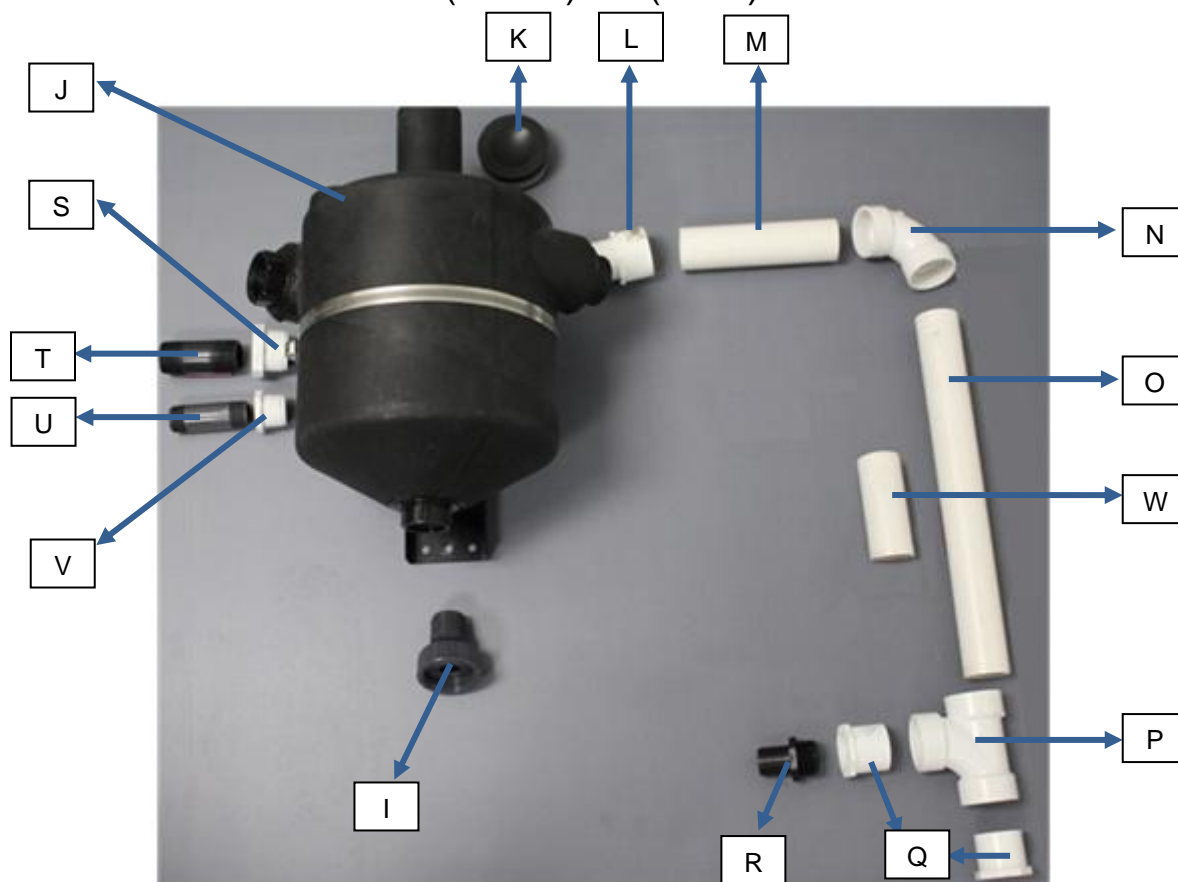
All components listed and described in this chapter are available as repair parts.

amalsed® direct S – Wet (In-line) Kit:



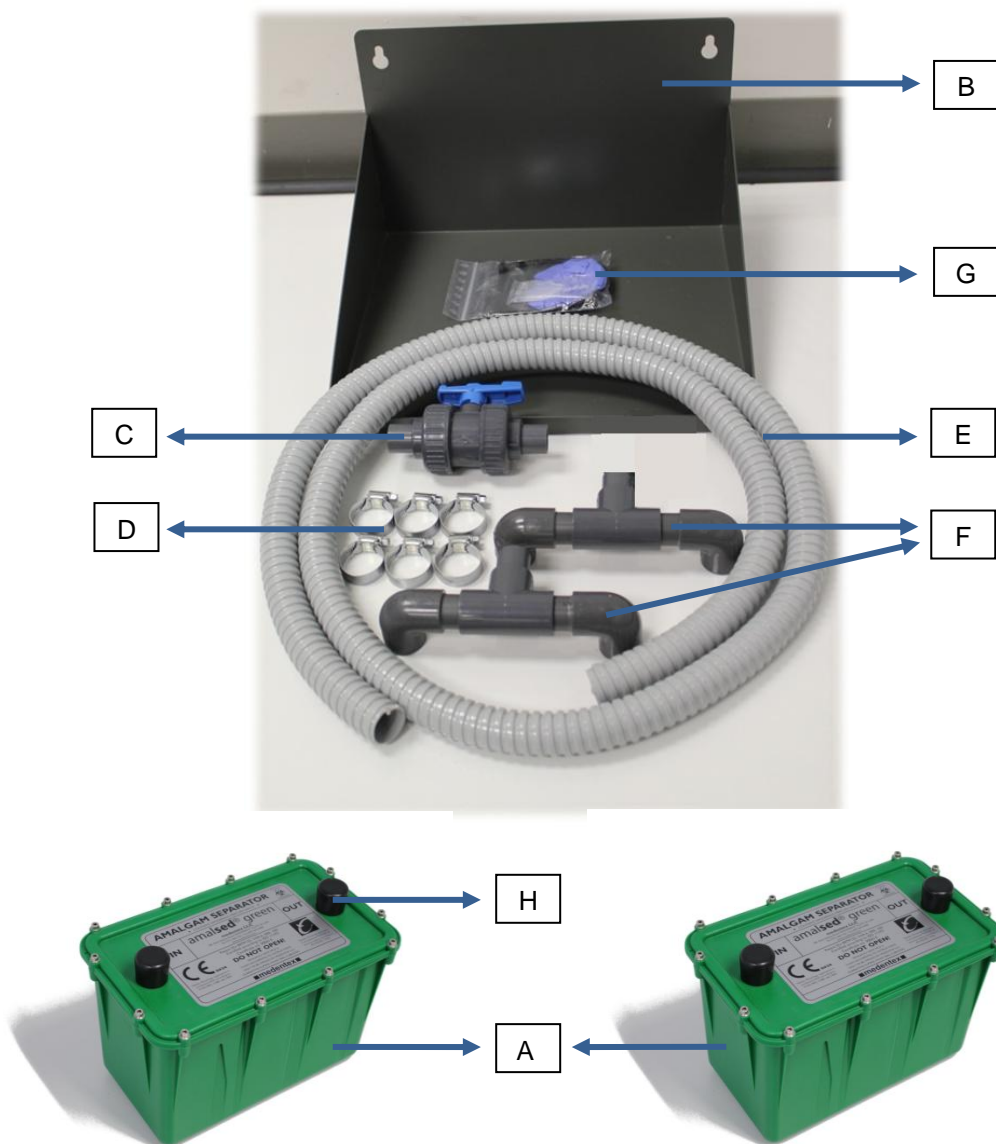
ITEM	NAME	TYPE	ARTICLE ID	QTY
A	Amalgam Separator	amalsed® green	A0US0001	1
B	Tray	-	A0100002	1
C	Service Valve	1" slip fit ends	A1000051	1
D	Hose Clamps	-	A1000001	6
E	Hose	5' x 1" double walled	A1000009	1
F	90° slip fit hose adapter	1" male x 1" female	A1000053	2
G	Separator service pack	Gloves, Silicone	AUS00001	1
H	Separator cap	1" Female Slip Fit	A2200004	2

amalsed® direct S - Wet (In-line) Kit (cont.):



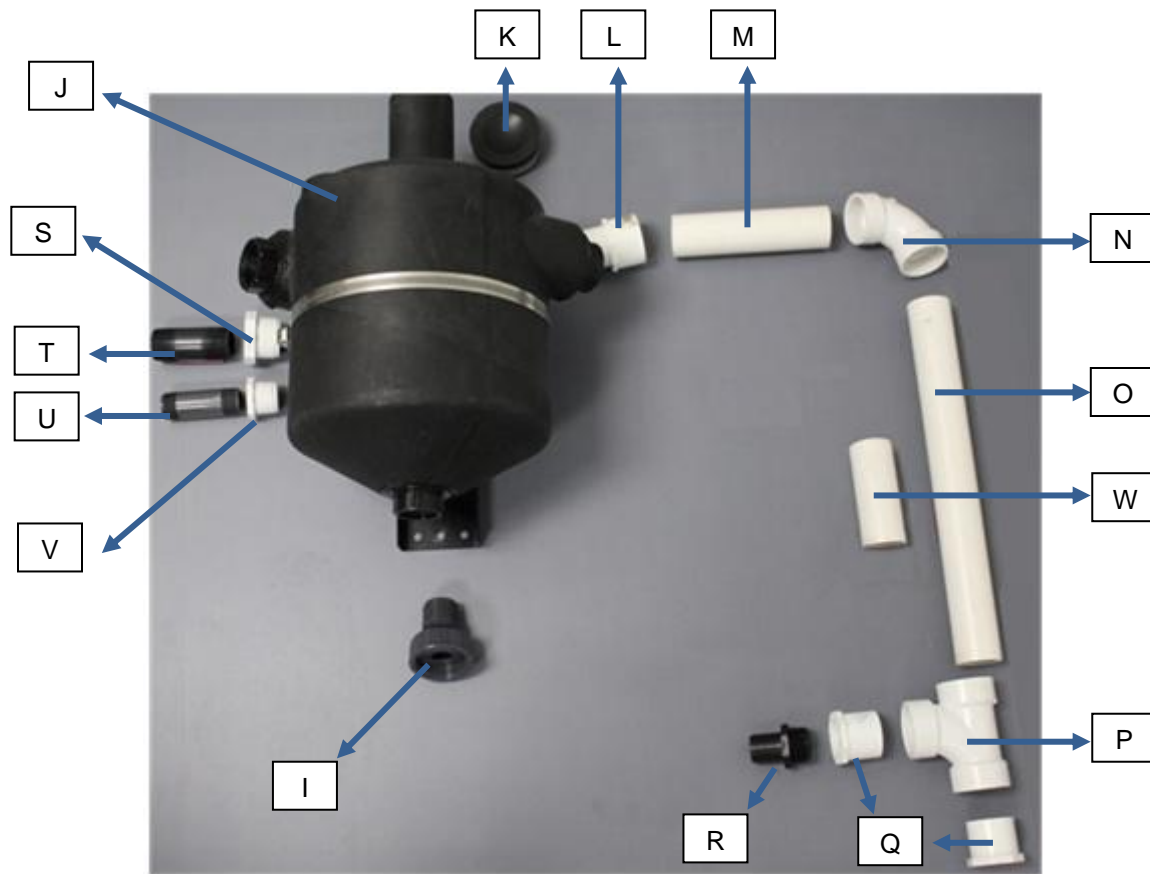
ITEM	NAME	TYPE	ARTICLE ID	QTY
I	Service valve adapter	1" MPT	A1000052	1
J	Air / Water separator (green)	Vacuum resistant tank	W0US0001	1
K	Rubber cap (if black A/W separator)	2" cap with tightening clamps	W0US0002	1
L	PVC adapter	1 1/4" MPT x 1 1/4" socket	W0US0003	1
M	PVC pipe	1 1/4" x approx.8"	W0US0004	1
N	90° PVC elbow	1 1/4" sockets	W0US0005	1
O	PVC pipe	1 1/4" x approx.15"	W0US0007	1
P	PVC Sanitary tee	1 1/4" hubs	W0US0008	1
Q	PVC adapter	1 1/4" spigot x 1" FPT	W0US0009	2
R	Hose adapter nipple	1" Barbed x 1" MPT	W0US0010	1
S	PVC Bushing reducer	1 1/4" MPT x 1" FPT	W0US0012	1
T	PVC nipple	1" MPT	W0US0013	1
U	PVC nipple	3/4" MPT	W0US0014	1
V	PVC Bushing reducer	1" MPT x 3/4" FPT	W0US0015	1
W	PVC pipe (optional)	1 1/4" x approx.4"	W0US00011	1

amalsed® direct L – Wet (In-line) Kit:



ITEM	NAME	TYPE	ARTICLE ID	QTY
A	Amalgam Separator	amalsed® green	A0US0001	1
B	Tray	-	A0100002	1
C	Service Valve	1" slip fit ends	A1000051	1
D	Hose Clamps	-	A1000001	6
E	Hose	5' x 1" double walled	A1000009	1
F	Plumbing Bridge	1" slip fit	A1000053	2
G	Separator service pack	Gloves, Silicone	AUS00001	1
H	Separator cap	1" Female Slip Fit	A2200004	2

amalsed® direct L - Wet (In-line) Kit (cont.):



ITEM	NAME	TYPE	ARTICLE ID	QTY
I	Service valve adapter	1" MPT	A1000052	1
J	Air / Water separator (green)	Vacuum resistant tank	W0US0001	1
K	Rubber cap (if black A/W separator)	2" cap with tightening clamps	W0US0002	1
L	PVC adapter	1 ¼" MPT x 1 ¼" socket	W0US0003	1
M	PVC pipe	1 ¼" x approx.8"	W0US0004	1
N	90° PVC elbow	1¼" sockets	W0US0005	1
O	PVC pipe	1 ¼" x approx.15"	W0US0007	1
P	PVC Sanitary tee	1 ¼" hubs	W0US0008	1
Q	PVC adapter	1 ¼" spigot x 1" FPT	W0US0009	2
R	Hose adapter nipple	1" Barbed x 1" MPT	W0US0010	1
S	PVC Bushing reducer	1 ¼" MPT x 1" FPT	W0US0012	1
T	PVC nipple	1" MPT	W0US0013	1
U	PVC nipple	¾" MPT	W0US0014	1
V	PVC Bushing reducer	1" MPT x ¾" FPT	W0US0015	1
W	PVC pipe (optional)	1 ¼" x approx.4"	W0US00011	1

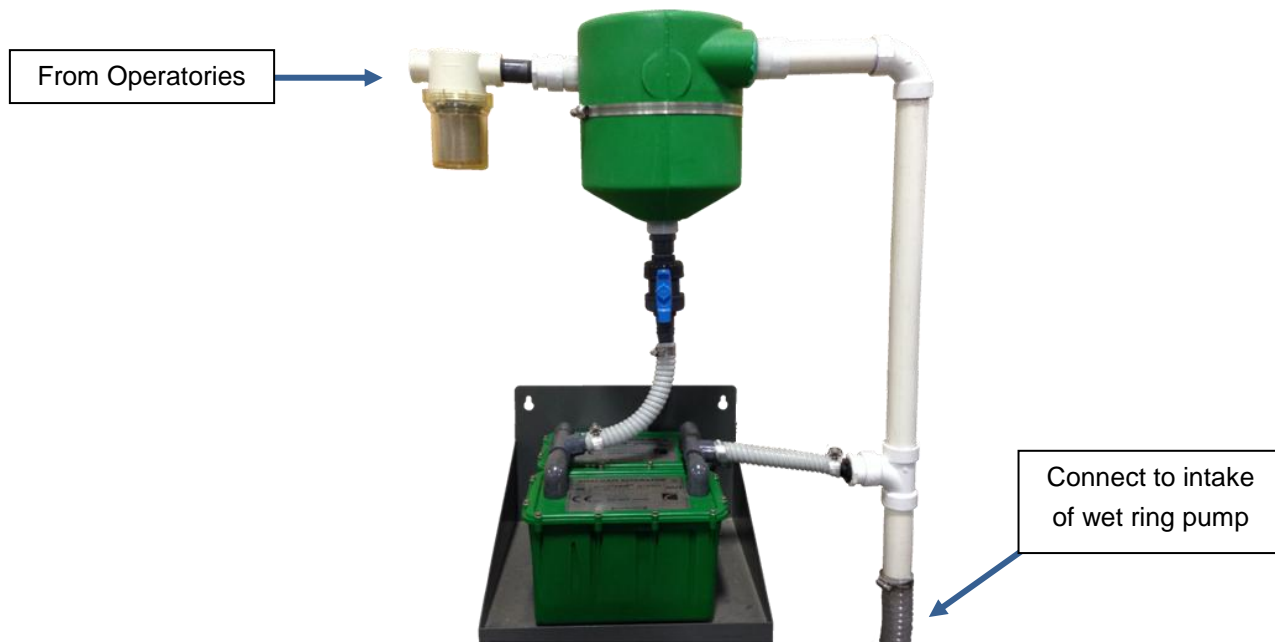
Installation



WARNING

- Always wear protective clothing when installing the amalsed[®] direct. Protective clothing includes protective gloves and protective mask.
- Shut down vacuum pump and allow existing system to drain.

amalsed[®] direct - Wet (In-line)*



1. Mount tray and buffer tank to wall in appropriate location with sufficient height distance .
2. Place amalgam separator on tray.
3. Place Solids Collector before buffer tank as shown above(use correct size bushings as needed)
4. Cut hose in two pieces with correct length for both, in-let and out-put to Drain or Sewer.
5. Push hose clamps over the hoses in natural lay of spiral hose
6. Connect hoses with adapter pieces and 90°connector pipe.
7. Fasten hose clamps in the right direction – Do not over tighten!
8. Install in-line to service valve (C) between tank and amalgam separator.
9. Connect output tubing of amalgam separator to drain or sewer or P-Trap
10. Make sure output tubing positioned to allow water to flow downwards. (see above)
11. Open service valve and test system for leaks!
12. Wet ring kit needs to be glued with primer and PVC glue.


*This set-up can also be used with a dry vacuum if preferred. (Must be installed in-line with air water separator as seen above)




NOTICE


Installation must comply with local plumbing codes! – Test system for leaks after installation!


Section IV – Care

	<p>NOTICE</p> <p>Please regularly verify if all connections are free of leakages. (View Section V for troubleshooting)</p>
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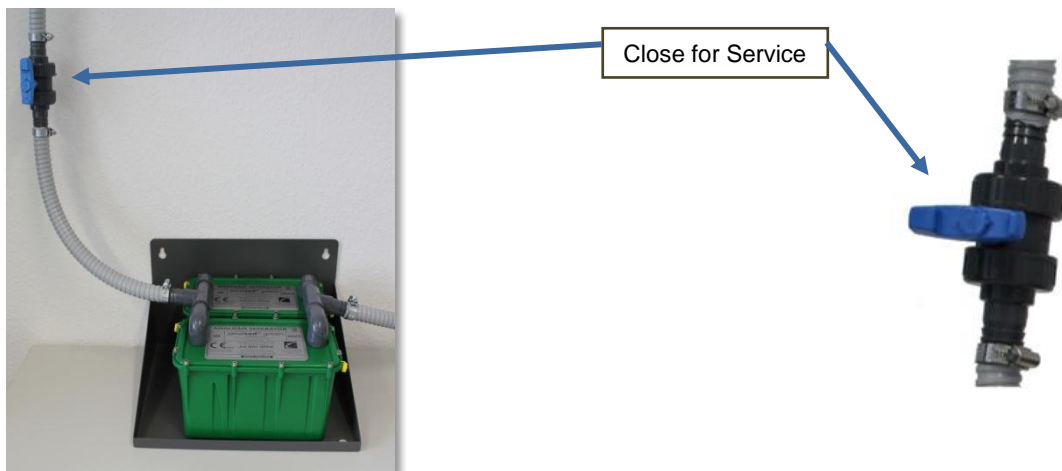
Replacing the amalgam separator

	<p>WARNING</p> <p>The amalgam separator can only be replaced by trained service technicians or by instructed members of the dental practice staff.</p>
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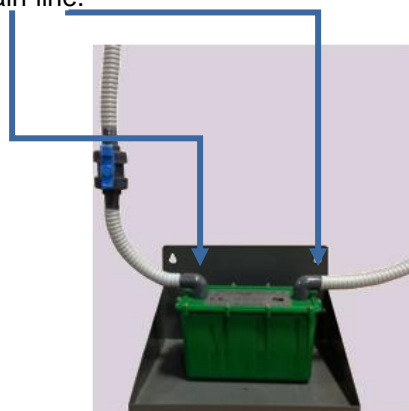
	<p>WARNING</p> <p>Wear protective clothing when replacing the amalgam separator. Protective clothing includes protective gloves, protective goggles and a laboratory coat.</p>
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	<p>NOTICE</p> <p>Do not allow the amalgam separator to exceed the maximum designated service life. medentex or a company authorized by medentex will inform you the service life of your amalgam separator when commissioning the amalsed® direct.</p>
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1. Before replacing the amalgam separator clean the suction system with a non-foaming cleaning agent for vacuum systems.
2. Shut down vacuum pump!
3. Close service valve. Wait 1 minute.



4. Detach both in-line and drain-line.



5. Close the inlet and outlet ports with original sealing caps. The sealing caps must clearly lock into place.



7. Before re-connecting the new amalgam separator(s), lubricate the o-rings on the intake/output ports. Reconnect the lines onto the ports of the amalgam separator(s).



6. Store the used amalgam separator in the original packaging.
medentex will arrange for pick-up service (free of charge)



8. Open service valve and restart vacuum pump.
9. Verify that all connections are tight and free of leaks!




NOTICE

Check that all connections are tight and do not leak before starting vacuum!

Cleaning and disinfecting agents

Safety-relevant notes on cleaning

To prevent microbiological contamination, the built up of deposits and soiling it is imperative that the suction hoses, waste water lines and the amalgam separation system are cleaned daily with special cleaning agents for dental suction systems.

	CAUTION
	Use only generally accepted cleaning agents for dental suction systems. medentex recommends the use of non-foaming and bleach/chlorine free cleaning agents.
	Carefully follow the directions on the cleaning agent of your choice.
	Only practice personnel that have received appropriate instructions may apply the cleaning agent. medentex highly recommends non-foaming cleaning agents. Please clean your suction lines daily and see User's log: daily cleaning actions, attached at the end of this document.

Section V – User Service Information

The following troubleshooting charts should be used when attempting to solve amalsed® direct operational problems. If the problem is not addressed in the trouble shooting chart or cannot be isolated by performing the suggested procedures, contact medentex or your local medentex full-service dealership.

Individual Product Information

Be prepared to supply the following product information:

Model Name:	
Article Number:	
Serial Number:	
Installation Date:	

Troubleshooting

Amalgam separation starter kit				
SYMPTOM	POSSIBLE CAUSE	SOLUTION	T ¹	PS ²
Drain line blocked	Separator clogged	Inform medentex and exchange separator immediately	x	x
Leakages at connections	Lose hose clamps	Tighten all hose clamps and dry system from outside to detect leakages immediately.	x	
	Damaged or faulty components	Exchange damaged / faulty components	x	
Service valve clogged or does not turn	Service valve clogged	Unscrew Service valve-head and rinse		x
		Detach service valve to clean, replace service valve if necessary	x	

¹ Technician

² Practice Staff

Section VI - Warranty & Product Support Services

In the event that you experience difficulty with the application or operation of any of our products, please contact our customer service department at 888-640-2527 or e-mail to info@medentex.com. Please note serial numbers of your product.

If we cannot resolve the issue by telephone, we will arrange for a representative to contact you.

All medentex products are intended for use solely by licensed dentist. Provided that the end user dentist complies with the instructions provided by or on behalf of the manufacturer and/or medentex, medentex warrants all amalsed® products to be free of defects in material and workmanship from the date of installation for a period of three (3) years on complete unit and five (5) years on all pumps, motors and housings, subject to the following terms and conditions.

These warranties shall cover the replacement or repair, at the option of medentex, for manufacturing defects only. The warranties shall not cover defects or damage resulting from misuse, improper handling, maintenance, or care, correction of improper installation, repair of damage due to improper installation, deterioration due to normal wear and tear, abuse, negligence, accidents, damage in transit, abnormal use, improper cleaning, or failure to comply with operating, maintenance or installation instructions. Failure to use medentex or manufacturer authorized parts or a medentex authorized repair facility voids this warranty.

Liability is limited to repair or replacement of the defective product and shall be at the discretion of medentex. All other liabilities, in particular liability for damages, including, without limitation, consequential or incidental damages, are excluded. These warranties are in lieu of all other warranties, express or implied, including any implied warranties of merchantability, fitness for a particular purpose, design or suitability. Except for the express warranty described herein, medentex makes no warranty, guarantees or representations with respect to the products covered hereby, express or implied, including, but not limited to, any warranty of merchantability, fitness for a particular purpose, design or suitability with respect to the products or any other goods, services or other materials provided by medentex.

medentex's sole liability shall be limited to repair and replacement of defective parts pursuant to the warranty described above and in no event shall medentex be liable for any damages, liability, or expense, including without limitation, attorney's fees, loss of profits, or indirect, special, consequential, incident or punitive damages, even if medentex was advised of the possibility of such damages.

Parts repaired or replaced on a product that is in warranty will be warranted for the duration of that product's original warranty.

NO EMPLOYEE, REPRESENTATIVE, AGENT, OR DISTRIBUTOR IS AUTHORIZED TO CHANGE THIS WARRANTY IN ANY WAY OR TO GRANT ANY OTHER WARRANTY.

User's log - Daily cleaning actions

[illegible]



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